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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,630	06/03/2005	Louis-David Cantin	5150	4617

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EXAMINER	
BIANCHI, KRISTIN A	

ART UNIT	PAPER NUMBER
1626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,630	CANTIN ET AL.	
	Examiner	Art Unit	
	KRISTIN BIANCHI	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,8-38 and 40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,3,6,8-13,16,19,24,25,36,38 and 40* is/are allowed.

6)☒ Claim(s) *4,5,14,17,20-22,26,29,30,32-35 and 37* is/are rejected.

7)☒ Claim(s) *15,18,23,27,28 and 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/14/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 3-6, 8-38, and 40 are pending in the instant application. Claims 2, 7 and 39 have been cancelled by way of amendment filed on March 20, 2009. Claims 4, 5, 14, 17, 20-22, 26, 29, 30, 32-35, and 37 are rejected. Claims 15, 18, 23, 27, 28, and 31 are objected. Claims 1, 3, 6, 8-13, 16, 19, 24, 25, 36, 38, and 40 appear to be allowable.

Information Disclosure Statement

The information disclosure statement filed on April 14, 2009 was considered and a signed copy of form 1449 is enclosed herewith.

Election/Restrictions

Upon further consideration, Groups X-XV (i.e., the method claims 14-37) have been rejoined.

Response to Amendment and Remarks

The amendment and remarks filed on March 30, 2009 have been fully considered and entered into the application. In regards to the 35 U.S.C. 102(e) rejection of claims 1, 2, 10-13, 37, 38, and 40 as being anticipated by Lowe et al., the grounds for rejection are moot in view of Applicant's amendment and the 35 U.S.C. 102(e) rejection has been withdrawn. In regards to the 35 U.S.C. 101 rejection of claim 39, the grounds for rejection are, again, moot in view of Applicant's amendment and the rejection has been withdrawn. In regards to the objection of claims 3-9, the grounds for objection are moot in view of Applicant's amendment and the objection has been withdrawn. However, this amendment has necessitated new grounds of rejection under 35 U.S.C.

112, 2nd paragraph, which are described below. Also, the previously withdrawn method claims, 14-37, have been rejoined and this has necessitated new grounds of rejection under 35 U.S.C. 112, 1st paragraph, which are described below.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claims 4 and 5 recite the limitation "Ar is phenyl" in the claims. There is insufficient antecedent basis for this limitation in the claims because claim 1 (from which these claims depend) has been amended to include only a 6-membered heteroaryl ring in the definition for Ar.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 17, 20-22, 26, 29, 30, 32-35, and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

The state of the prior art and the predictability or lack thereof in the art

The term “prevention" or "prophylaxis” actually means to anticipate or counter in advance, to keep from happening, etc. and there is no disclosure as to how one skilled in the art can reasonably establish the basis and the type of subject to which the instant compounds can be administered in order to have the "preventative" effect. Therefore, it is recommended that the terms “preventing” and "prophylaxis” be removed from the claims (i.e., claim 37).

The state of the prior art is that the pharmacological art involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e., what compounds can treat which specific disease or condition by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d

833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statue. In the instant case, the instantly claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic effects, whether or not the disease or condition is affected by the administration of the compounds of the instant claims would make a difference.

In regards to the methods of treating **diabetes**, **diabetes-related disorders** and **cardiovascular diseases**, the methods are too broad as written (i.e., the diseases or disorders which can be included in the methods are too numerous). There is not one class of compounds, let alone one compound, which can treat all of the diseases or conditions which would be included in the methods listed above. It is recommended that the claims be amended to include the specific types of diabetes (i.e., those listed in claim 15), diabetes-related disorders (i.e., those listed in claim 18) and cardiovascular diseases (i.e., those listed in the specification in paragraph [0735] or atherosclerosis, coronary heart disease, coronary artery disease, and hypertension) which can be treated by the methods. The same goes for claim 37. In regards to the methods of treating or preventing **secondary cases of diabetes**, these methods could include many unrelated diseases or conditions (i.e., many of which have a different cause and, therefore, require a different treatment). There is not one class of compounds, let alone one compound, which can treat or prevent all of the diseases or conditions which would be included in these methods. It is recommended that the claims (i.e., claims 32-35) which include these methods be deleted.

The amount of direction or guidance present and the presence or absence of working examples

Applicant has not provided any competent evidence or disclosed tests that are highly predictive for the broad methods of treating **diabetes**, **diabetes-related disorders** and **cardiovascular diseases** or the broad methods of treating or preventing **secondary cases of diabetes**, and pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

The level of skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by i*n vitro* and *in vivo* screening to determine which compounds exhibit the desired pharmacological activity and which diseases or conditions would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compounds of the instant claims for the treatment or prevention of the various claimed disorders or conditions, as a result necessitating one of skill to perform an exhaustive search for which disorders or conditions can be benefited by what compounds of the instant claims in order to practice the claimed invention.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what specific disorders or conditions are benefited by the administration of the compounds of the instant claims and would furthermore have to determine which of the claimed compounds would provide treatment of which diseases or conditions.

Factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instantly claimed methods. In view of the chemical nature of the invention and the lack of working examples regarding the activity of the claimed compounds, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which specific disorders or conditions can be treated by the compounds encompassed in the instant claims, with no assurance of success.

Other Matter

It is recommended that the word "prophylaxis" be deleted from claim 40 and also that the specific types of diabetes (i.e., those listed in claim 15) be included in the claim for the reasons give above.

Claim Objections

Claims 15, 18, 23, 27, 28, and 31 are objected for depending on a previous rejected base claim.

Allowable Subject Matter

Claims 1, 3, 6, 8-13, 16, 19, 24, 25, 36, 38, and 40 appear to be allowable (i.e., no prior art was found).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTIN BIANCHI whose telephone number is (571)270-5232. The examiner can normally be reached on Mon-Fri 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kamal A Saeed/
Primary Examiner, Art Unit 1626

Kristin Bianchi
Examiner
Art Unit 1626

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